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**From:** Dourson, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB29BF491D9A4C3AB569022BCD205A0A-DOURSON, MI]  
**Sent:** 11/2/2017 5:27:19 PM  
**To:** Greaves, Holly [greaves.holly@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]  
**Subject:** Re: IRIS/TSCA

Holly, Nancy and Richard

I have talked with a number of senior risk assessment career EPA staff over the years regarding improvements to IRIS. Many, and perhaps all, of them would agree that a new approach is needed and, furthermore, that a senior agency group who worked to get all agency risk assessment values on IRIS would be helpful now, as it was in the past. This senior group could be composed quite easily, and if run out of the administrator's shop, at least temporarily, would be one way to mollify outside critics of the system.

I would be more than happy to work up a straw-person for such a group if this is helpful for our discussion tomorrow.

Cheers!

Michael

Sent from my iPad

On Nov 1, 2017, at 10:07 AM, Dourson, Michael <dourson.michael@epa.gov> wrote:

Holly, thanks for the invitation to participate. I am looking forward to it.

Richard, congratulations on getting the boards announced. Very nice.

Cheers!

Michael

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**From:** Greaves, Holly  
**Sent:** Wednesday, November 1, 2017 9:38 AM  
**To:** Dourson, Michael <dourson.michael@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>  
**Subject:** RE: IRIS/TSCA

Good morning,

I'd like to re-visit this issue with the 3 of you now that the Boards have been announced.

The best time appears to be Friday at 2:30 (Nancy, I see you will have to leave early – if you'd prefer to call-in instead, please let me know).

Thanks,  
Holly

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**From:** Dourson, Michael  
**Sent:** Tuesday, October 24, 2017 7:31 AM  
**To:** Greaves, Holly <[greaves.holly@epa.gov](mailto:greaves.holly@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Subject:** RE: IRIS/TSCA

Holly

I do not see IRIS becoming the agency risk value database again until:

- <!--[if !supportLists]--><!--[endif]-->Senior management states its expectation that all agency risk assessment values that merit senior agency review are to be on IRIS.
- <!--[if !supportLists]--><!--[endif]-->A senior agency workgroup, independent of any agency office, is formed to review and clear values for placement on IRIS.
- <!--[if !supportLists]--><!--[endif]-->This workgroup is composed of EPA's most experienced risk assessors, one or two from each EPA office that estimates risk values.

It seems reasonable that the workgroup would be administratively housed in the Administrator's office. However, it worked well before run out of NCEA-Cincinnati from 1986 to 1995. So, it might also run well out of either NCEA or OCSPP now. But in either case, an independent senior agency workgroup is needed, and importantly, the final call on any risk value is left to this agency group, and not to managers who are not otherwise astute in risk value determination (although several agency scientists are both).

My impression is that OCSPP has a lot of work to do over the short time frame, and with even minimal budget restrictions, taking on IRIS would be difficult, if not impossible, without the current resources devoted to IRIS.

Cheers!

Michael

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**From:** Greaves, Holly  
**Sent:** Monday, October 23, 2017 11:52 AM  
**To:** Dourson, Michael <[dourson.michael@epa.gov](mailto:dourson.michael@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Subject:** RE: IRIS/TSCA

Dr. Dourson, thank you so much – this is really a helpful starting point.

From the comments below, and my knowledge of the program, the summarized options that we have are as follows:

1. <!--[if !supportLists]--><!--[endif]-->Through an interagency working group (essentially the options laid out below)
2. <!--[if !supportLists]--><!--[endif]-->Merge with TSCA
3. <!--[if !supportLists]--><!--[endif]-->Continue to provide Tina with resources to fully implement the reforms currently underway

Does this group feel that we could take these options to Ryan to obtain his direction on how to move forward? If we do that, it would be helpful to have consensus among this group to provide Ryan with one recommendation from potential options.

Please let me know.

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**From:** Dourson, Michael

**Sent:** Saturday, October 21, 2017 12:42 PM

**To:** Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Greaves, Holly <[greaves.holly@epa.gov](mailto:greaves.holly@epa.gov)>

**Subject:** Re: IRIS/TSCA

Dear Holly, Nancy and Richard

Thanks for including me in the IRIS discussion. As one of the first IRIS leaders I have been concerned about it ever since the late 1990s. What follows is a sketch that outlines 3 items, roughly described at the good, the bad, and the possible!

I would be more than happy to flesh these musings out along with a lot of input from you and other colleagues in EPA.

Cheers!

Michael

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#### The Good

- IRIS started in 1986 after the formation of an intraagency work group that was devoted to harmonizing RfDs throughout EPA. After a contentious start where 39 of 40 RfDs from different offices disagreed, the RfD/RfC work group developed into a high energy and high throughput organization, meeting every month to clear up to about 10 assessments. 500 files were loaded to IRIS within 5 years.
- The best risk assessment scientists composed the work group; each program donated up to 0.1 or 0.2 FTE towards the WG. NCEA in Cincinnati organized the work group at 0.3 FTE.
- Each program office brought in their RfDs for review. The face to face (FTF) meetings and discussion constituted the agency review. Contentious issues were thrashed out in person, with disagreements scheduled for resolution at a subsequent meeting. Importantly, managers were not a part of this process; rather senior risk assessment scientists were given authority to make decisions.
- Younger risk assessors were brought in to present in front of the work group. Younger staff learned a lot from interactions with senior work group members.
- An intraagency cancer group formed in 1987 called CRAVE (Carcinogen Risk Assessment Verification Endeavor) with equal success.
- Interest in IRIS picked up when values were given to US state staff, but with little devoted resources, outside comments could not be fully addressed.

#### The Bad

- The work groups (both RfD/RfC and CRAVE) were disbanded in mid 1995 for the stated purpose of efficiency.
- Without these two intraagency work groups, face-to-face communication among offices was reduced, and many risk values once again were developed without significant input. Currently, IRIS IS NOT EPA's most current list of risk information, and even has significantly less information than in 1990.
- Opportunities for younger staff to learn risk assessment from senior work group members became more limited. Currently, risk assessment training among agency offices does not appear to be consistent.
- Without FTF senior agency scientists' review and senior risk assessor oversight, risk assessment judgments in the IRIS program became uneven. Some were very good, others were very bad; some were mediocre.

- Outside comments on the IRIS judgments that were bad or mediocre slowed the process down considerably.
- Written reviews by EPA scientists also slowed down the process considerably, since memos had to be written and cleared through EPA management. Senior risk assessment scientists' comments were often ignored. Under the prior work group process, such disagreements were thrashed out FTF among senior risk assessors, and resolution occurred within months.

#### The Possible

- The concept of IRIS as the agency repository of risk assessment values is good. EPA and others benefit greatly by having one place for current risk assessment information.
- Agency staff would benefit from sharing risk information among offices, especially if it has been peer reviewed by a senior group of EPA scientists.
- Options to go forward (among many):
  - 1) Recreate one senior agency work group. Keep control of this group in the office of the Administrator, thus placing high value to the continuation of IRIS for public stakeholders.
  - 2) Open up IRIS to all agency risk assessment values that merit senior agency review, with the work group meeting FTF once a month to clear risk assessments.
  - 3) Current risk assessments are more complex than in the late 1980s. Thus, it would be expected that fewer assessments can be cleared per month. Moreover, IRIS has legacy chemicals that are woefully out of date, important assessments are not on IRIS, and new chemicals assessments are being developed that need EPA review. Biweekly meetings may be needed over the first year to clear this backlog, and to allow new information to be reviewed in a timely manner.
  - 4) GAO recommendations to move IRIS to OCSPP appear to be based on the feeling that senior NCEA management cannot handle astute risk assessments. This may be true to some extent, but may also be true to some extent for any agency office, including OCSPP. This is because risk assessments now are more complex than any one scientist, or even one group, can hope to address. In contrast, an agency wide group composed of senior risk assessment scientists would (again) provide the erudition and oversight needed to address internal differences of opinion, and outside comments and concerns as appropriate.

Sent from my iPad

On Oct 19, 2017, at 7:14 PM, Dourson, Michael <[dourson.michael@epa.gov](mailto:dourson.michael@epa.gov)> wrote:

Thanks!

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**From:** Beck, Nancy  
**Sent:** Thursday, October 19, 2017 7:51 AM  
**To:** Dourson, Michael <[dourson.michael@epa.gov](mailto:dourson.michael@epa.gov)>  
**Subject:** FW: IRIS/TSCA

FYI—background for Friday. I can give you more info as well.

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**From:** Greaves, Holly  
**Sent:** Wednesday, October 18, 2017 10:11 AM  
**To:** Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Yamada, Richard (Yujiro)

<yamada.richard@epa.gov>

**Subject:** IRIS/TSCA

Good morning,

The political Associate Director at OMB reached out again today about the possibility of merging IRIS and TSCA. I'm copying his comments below. I would like to set up a call with him and the 3 of us.

Would you be free at noon on Friday?

Thanks,  
Holly

*We've been lobbied by a few groups to consolidate the programs and have had conversations with the appropriations committees about it. Majority staff on the committees all seem fine with merging the two programs, but they're waiting on the Administration to make a proposal before they act. Last time I spoke with Mulvaney about it, he was fine with consolidation.*

*Our general approach to budgets has been to reduce or eliminate duplication wherever it exists and IRIS seems to fit into this category. I find it difficult to explain to the lay person why we need two separate chemical programs at EPA. People don't understand why a single program can't do all the work that's necessary.*

*Ideally, I want to get OMB and EPA on the same page on this, so if you all have concerns about a merger, now would be the time to talk with us.*